



R. J. COLLEGE of Arts, Science & Commerce (AUTONOMOUS)

(Hindi Vidya Prachar Samiti's RAMNIRANJAN JHUNJHUNWALA COLLEGE of Arts, Science & Commerce)

Opposite Ghatkopar Railway Station, Ghatkopar (West), Mumbai 400086, Maharashtra, INDIA.

Website: www.rjcollege.edu.in Email: rjcollege@rjcollege.edu.in Tel No: +91 22 25151763 Fax No: +91 22 25150957

College is recognized under Section 2(f) & 12(B) of the UGC Act, 1956

Affiliated to UNIVERSITY OF MUMBAI II NAAC Re-Accredited 'A' Grade (CGPA: 3.50)

13/06/2019

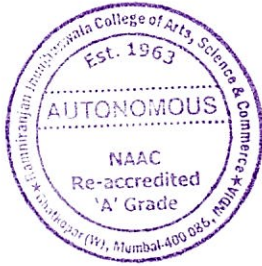
ADMISSION NOTICE FOR POST GRADUATE DIPLOMA PROGRAMS 2019-2020

DEGREE COLLEGE

The admissions of Post Graduate Diploma programs in-

1. Dietetics and Applied Nutrition
2. Regulatory Affairs
3. Clinical Studies Data Management and Medical Writing
4. Horticulture and Landscape Designing

will commence from 1st July 2019. Students must fill the form. The eligibility criteria and fee structure is available on the college website. Admission will be on fulfilment of criteria. Students must pay the fees.



Usha
Principal

PRINCIPAL
RAMNIRANJAN JHUNJHUNWALA COLLEGE
OF ARTS, SCIENCE & COMMERCE (AUTONOMOUS)
Ghatkopar (W), Mumbai-400 086, Maharashtra, INDIA

2019: Star College Status by DBT

2008: Best College by University of Mumbai 2010: IMC RBNQ Award 'Performance Excellence' for the year 2009

2011: 'Best Teacher Award' by Government of Maharashtra 2013: DST-FIST 2014: DBT STAR College

2013 & 2014: 'Jagar Jaanivancha Award' by Govt, of Maharashtra 2016: ISO 14001:2015 2016: ISO 9001:2015 2017: ISO 27001:2013

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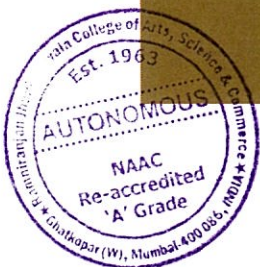
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BROCHURE



Postgraduate Diploma in

Clinical Studies, Data Management & Medical Writing



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Academic Council 25/05/2011

Item No. 4.71

UNIVERSITY OF MUMBAI



Syllabus for Clinical Studies
Program: Diploma
Course: Post Graduate Diploma
in
Clinical Studies, Data Management & Medical Writing

(Introduced as per Credit Based Semester and Grading System with effect from the academic year 2011–2012)



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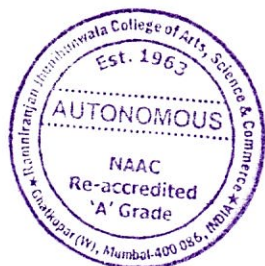
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- O Title** : Post Graduate Diploma in Clinical Studies, Data Management and Medical Writing
- O Eligibility** : Bachelor Degree in Life Science or Biotechnology or Chemistry or Statistics
- R Duration of the Course** : One Year (Full Time/)
- R Fee Structure** : Rs. 30000/-
- R Intake Capacity** : 40 Students
- R Teacher Qualifications** : Completed Course in Clinical Studies and Experts from Clinical Research or Pharma industry
- R Standard of Passing** :
- Candidate who secures minimum 50% marks in each paper be declared to have passed the examination in that subject.
 - A candidate who fails to secure 50% marks in a paper will be allowed to reappear in that paper.
 - Candidate can carry forward at his/her option the marks in the paper in which he/she has passed, in such a case student is entitled for award of class.
 - Candidate who secures a minimum of 50% marks in each paper and an aggregate of 60% and above marks on the whole shall be declared to have passed the examination in the First Class.
 - Candidate who secures a minimum of 50% marks in each paper and an aggregate of 70% and above marks on the whole shall be declared to have passed the examination in First Class with Distinction.

Medium of Instruction : English

Field Visit : Clinical Research Organizations



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Syllabus for Post Graduate Diploma

in

Clinical Studies, Data Management and Medical Writing Scheme of Examination

PAPER	TITLE OF PAPER	MAXIMUM MARKS	MINIMUM MARKS	Credits	PAPER CODE
I	Clinical Pharmacology	100	50	8 Credits	PGDCS001
II	Good Practices & Regulations	100	50	8 Credits	PGDCS002
III	Clinical Trial Process	100	50	8 Credits	PGDCS003
IV	Drug Safety & Pharmacovigilance	100	50	8 Credits	PGDCS004
V	Data Management & Medical Writing	100	50	8 Credits	PGDCS005
VI	Management Skills	100	50	8 Credits	PGDCS006
	TOTAL	600	300	48 Credits	

(All papers include theory, viva, project and case studies)

Syllabus for Post Graduate Diploma

in

Clinical Studies, Data Management and Medical Writing

Paper I	: Clinical Pharmacology
Paper II	: Good Practices & Regulations
Paper III	: Clinical Trial Process
Paper IV	: Drug Safety & Pharmacovigilance
Paper V	: Data Management & Medical Writing
Paper VI	: Management Skills




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Paper I : Clinical Pharmacology

8 Credits

1. **Pharmaceutical Industry & globalization** –Overview, Opportunities & Career options in Clinical Research
2. **Pharmacy** - Physico-Chemical properties of drugs, different drug dosage forms, Formulation development and manufacture of drugs.
3. **Therapeutics** - Principles of Management & Drug Therapy
4. **Pharmacokinetics** - Absorption, bioavailability, distribution, metabolism protein binding, excretion, placental and blood brain barrier
5. **Pharmacodynamics** - Mechanism of drug action, receptors, agonists, antagonists, side effects and adverse events
6. **Toxicology** - Acute, Sub-acute and Chronic Toxicity, Mutagenicity, Teratogenicity, Oncogenicity and effects on fertility
7. **BA/BE Studies** - Bioavailability and Bioequivalence - Methods and Procedures, regulatory requirements, planning & design, Protocol/ CRF outline, QA & QC, Drug accountability



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Paper II : Good Practices & Regulations

8 Credits

GMP
GLP
ICH GCP
Ethics in Clinical Research
Regulation in India : Drugs and Cosmetics Act, Schedule 'Y', Quality in Regulatory Context, Patent laws
USFDA : History, Structure & Function, Code of Federal Regulation
EMA : History, Structure & Function, Regulations
JAPAN : History, Structure & Function
ICMR : Overview

Paper III : Clinical Trial Process

8 Credits

1. Responsibilities of Stakeholders : Sponsors, Investigators, CROs, Monitors
2. Clinical Trial Design
3. Clinical Trial Phase I
4. Clinical Trial Phase II
5. Clinical Trial Phase III
6. Clinical Trial Phase IV
7. Essential Documents in Clinical Trials : SOP, Protocol, Investigator Brochure, Master Files, Informed Consent Forms, Case Record Form
8. Managements of Clinical Trials - Investigator's Meeting, Project management, Patient Recruitment & Retention, Trial Monitoring, Drug Resource and supplies
9. Trial Budget, Audit and Inspection



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Paper IV : Drug Safety & Pharmacovigilance

8 Credits

1. **Principles of Pharmacovigilance** : Importance; National & International Programs; Methods
2. **Principles of Pharmacovigilance** : ADR; Assessment; Medication errors, Signal detection; Risk assessments
3. **Drug Dictionaries**: Coding & Tools
4. **Regulatory Guidelines** : ICH, EMEA, USFDA, Sch. 'Y'
5. **Drug Safety** : PSURs; Package inserts

Paper V : Data Management & Medical Writing

8 Credits

1. **Bio-Statistics : Descriptive Statistics** : Data Types; Collection; Sampling, Compilation; Tables & Graphs, Measures of Central Tendency, Measures of variation
2. **Bio-Statistics : Analytical Statistics** : Overview, hypothesis testing in CR
3. **Clinical Data Management** : Principles of CDM, Data Entry, Queries & Data Clarification, Softwares in CDM
4. **Medical Writing** : Literature Search & Medical Articles, Contract writing, Publication, Abstracts, Bibliography, Clinical Study Reports




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Paper VI Management Skills

8 Credits

1. Principles of Management
2. Management & relevance to CR
3. Introduction to Organization behavior
4. Introduction to Marketing
5. Introduction to Business environment
6. Aptitude Tests

Language & Vocabulary

Spelling

Comprehension

Numerical

Reading

7. Effective communication skills

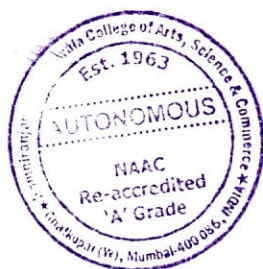
- Process
- Types/Barriers
- Business Language writing
- E-mail writing
- Report writing

8. Public speaking

9. Presentation skills

10. Self Management & People Skills

- SWOT, Self Motivation
- Emotional Intelligence



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- Being Assertive
- Working together- team member
- Time management
- Managing conflicts
- Developing Leadership skills
- Creativity & Innovation
- Cross cultural skills

11. Corporate etiquettes & workplace behavior

12. Developing Personal Impact

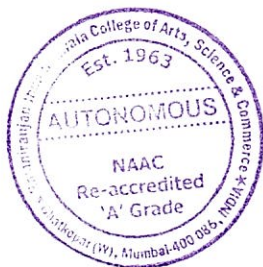
13. Interviews Skills and etiquettes & mock sessions through FAQs.

14. Group Discussions

15. Writing compelling CV and covering letter

List of Reference Books :

1. Research in education by J W Best and J V Khan Prentice Hall of India, New Delhi (1995).
2. Pharmaceutical Statistics by Sanford Bolton, Marcel Dekker, New York, USA, Informa Healthcare: 4 edition (October 17, 2003).
3. Elementary Statistical Quality Control, Volume 25, Burr, I. W. (1979), New York: Marcel Dekker, Inc.
4. Managing the clinical drug development process, C. Nardi, Marcel Dekker, New York, USA (1991).
5. Basic managerial skills for all by E H Mcgrath, Prentice Hall of India, N.Delhi (2002).
6. Organizational Behavior. John W Newstrom, Keith Davis, Tata McGraw Hill, New Delhi (2002)



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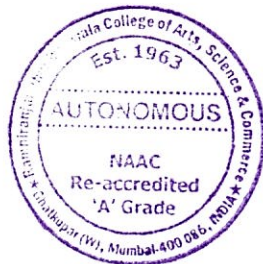
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7. Clinical Research Environment in India by Umakanta Sahoo, Faiz Kermani, ICFAI University Press (2008).
8. Clinical Trials. Lelia Duley and Barbara Farrell (eds), BMJ Books, London, 2002.
9. Handbook for good clinical research practice WHO Library Catalogue.
10. Artciles: ICH-GCP, Schedule Y, US FDA guidelines, WHO Guidelines.
11. Bioavailability and Bioequivalence in pharmaceutical technology by Tapan Kumar and Ganeshan M. CBS publishers and distributors(2006).
12. Design of experiments. A realistic approach by V L Anderson and Robert Mclean. Marcel Dekker, New York, USA (1974).
13. Fundamentals of Clinical Research: Bridging Medicine, Statistics and Operations. Antonella Bacchieri and Giovanni Della Cioppa, Springer (2007)



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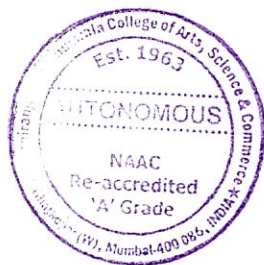
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PG Diploma in Clinical Studies, Data Management and Medical Writing

REPORT

The PG Diploma in Clinical Studies, Data Management and Medical Writing commenced on 20th July 2019 with an orientation about the course by Dr. Archana Shirpurkar the course coordinator. Eminent faculty Dr. Vishal Narang, Dr. Amey Mane, Mr. Sagar Vaidya trained the students. The program was conducted in two semesters semester I and Semester II. All students had to attend the continuous evaluation, and semester end examinations for qualifying for the PG Diploma Program. 49 students successful completed the program.



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(Hindi Vidya Prachar Samiti's) **RAMNIRANJAN JHUNJHUNWALA COLLEGE of Arts, Science & Commerce**

Opposite Ghatkopar Railway Station, Ghatkopar (West), Mumbai 400086, Maharashtra, INDIA.

Website: www.rjcollege.edu.in

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Tel No: +91 22 25151763

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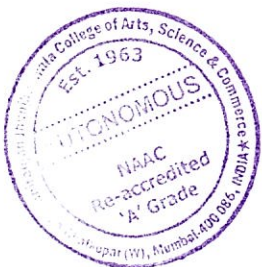
College is recognized under Section 2(f) & 12(B) of the UGC Act, 1956

Affiliated to UNIVERSITY OF MUMBAI || NAAC Re-Accredited 'A' Grade (CGPA: 3.50)

PG DIPLOMA IN CLINICAL STUDIES, DATA MANAGEMENT AND MEDICAL WRITING

LIST OF STUDENTS WHO COMPLETED THE COURSE

SR NO	NAME OF THE STUDENT	ROLL NO
1	CHAVAN AJIT	1
2	JAWKE AKANKSHA	2
3	SHINDE AKSHATA	3
4	BHOSALE ALISHA	4
5	JAKATE AMRUTA	5
6	GAIKWAD ANIKET	6
7	TANKARIA Anjaly	7
8	PAWAR ANKITA	8
9	PANDEY ANVEKSHA	9
10	SINGH ASHISHKUMAR	10
11	THOMBARE DHANASHREE	11
12	PAKHARE DIVYA	12
13	KHAN FAIZALAM	13
14	BAGATE HARSHAWARDHAN	14
15	YADAV JITESH	15
16	OVHAL KAJAL	16
17	MAHADIK KOMAL	17
18	GUPTA KOMAL	18
19	KAMBLI MANSI	19
20	DHOLAKIA NOOPUR	20
21	KANSE PANKAJ	21
22	DEOLEKAR POOJA	22
23	JOSHI POOJA	23
24	CHIVILKAR PRADNYA	24
25	THAKKAR PRANAV	26
26	SHIVADE PRITAM	27
27	HALDANKAR RADHIKA	28
28	GHADGE RESHMA	29
29	GURAV RUCHIRA	30
30	KAMBLE RUTUJA	31
31	MIRZA SAIMA	32
32	KOTIAN SHWETA	33
33	TODKAR SIDDHARTH	34
34	SITAP SIDDHI	35
35	TIWARI SNEHA	36
36	PATIL SOHA	37



C. J. J.

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OF ARTS, SCIENCE & COMMERCE (AUTONOMOUS)
Ghatkopar (W), Mumbai-400 086, Maharashtra, INDIA

2019: Star College Status by DBT

2008: Best College by University of Mumbai 2010: IMC RBNQ Award 'Performance Excellence' for the year 2009

2011: 'Best Teacher Award' by Government of Maharashtra 2013: DST-FIST 2014: DBT STAR College

2013 & 2014: 'Jagar Jaanivancha Award' by Govt. of Maharashtra 2016: ISO 14001:2015 2016: ISO 9001:2015 2017: ISO 27001:2013

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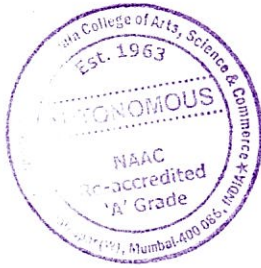
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37	KONAR SUGANYA	38
38	PARKHE SUPRIYA	39
39	GHOSAL SUSHMITA	40
40	AHUJA TANYA	41
41	ZADMALI TEJASVI	42
42	VADHAR VIDHI	43
43	PRAJAPATI VIDHI	44
44	BATTULA VINIT	45
45	KALE VINIT	46
46	QURESHI ZUBER	47
47	SINGH SUMEET	48
48	JAISWAR INDRAJEET	49
49	BORKHEDE DINESH	50



Usha

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Hindi Vidya Prachar Samiti's
RAMNIRANJAN JHUNJHUNWALA COLLEGE
of Arts, Science & Commerce
(Autonomous)

Affiliated to UNIVERSITY OF MUMBAI

CERTIFICATE OF MERIT



This is to certify that

CHAVAN AJIT VIJAY JYOTI

has secured

"A"

in Postgraduate Diploma in Clinical Studies Data Management and Medical Writing

in the examination held in Aug 2020.

Controller of Examination
CONTROLLER OF EXAMINATION
Ramniranjan Jhunjhunwala College of Arts, Science & Commerce
(AUTONOMOUS)
Ghatkopar (W), Mumbai-400 086, Maharashtra, INDIA



Principal
PRINCIPAL
RAMNIRANJAN JHUNJHUNWALA COLLEGE
OF ARTS, SCIENCE & COMMERCE (AUTONOMOUS)
Ghatkopar (W), Mumbai-400 086, Maharashtra, INDIA

Certificate ID: PGDCSDMMW-201920-01